PATENT
ATTORNEY DOCKET NO.: GENE1180-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Dev et al.	Art Unit:	Unassigned
Continuation Application No.:	**Unassigned**	Examiner:	Unassigned
Continuation Application Filed:	**December 14, 2001**		
Parent Application No.:	09/329,098		
Parent Filing Date:	June 9, 1999		
Title:	ELECTROPORATION-MEDIATED INTRAVASCULAR DELIVERY		

BOX PATENT APPLICATION
Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

This Preliminary Amendment is filed in conjunction with a Request for filing of a Continuation Application. Please consider the following amendments and remarks prior to prosecution of the Continuation Application:

In The Claims

Please enter claim 1 rewritten as follows:

EXPRESS MAIL Number: **EV 016236137 US**
Date of Deposit: **December 14, 2001**

I hereby certify that this paper is being deposited with the United States Postal Service "EXPRESS MAIL Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to: BOX PATENT APPLICATION, Commissioner for Patents, Washington, D.C. 20231

JASON BERRY
(Name of Individual Depositing with P.O.)

Jason Berry
(Signature of Individual Depositing with P.O.)

1. (Amended) An apparatus for introducing a composition into at least one cell in a vessel in a subject comprising:

a catheter having at least one inflatable balloon portion, wherein upon inflation, the balloon occludes the vessel;

at least one infusion [passage] opening for introducing the composition into the subject proximal to the at least one inflatable balloon portion;

a first electrode positioned adjacent to at least one infusion opening; and

a second electrode positioned with respect to the first electrode and the subject such that an electric field sufficient to cause electroporation of at least one cell [in the vessel is generated, thereby allowing the composition to enter at least one cell] after introduction of the composition through at least one infusion [passage] opening.

The following new claims 7-22 have been added:

7. (New) The apparatus of claim 1, wherein the catheter has two inflatable balloon portions.

8. (New) The apparatus of claim 7, wherein the at least one infusion opening is between the two inflatable balloon portions.

9. (New) The apparatus of claim 1 or 8, wherein the first electrode is coincident with the at least one infusion opening.

10. (New) A catheter comprising:

a first inflatable balloon portion near the distal end of the catheter;

a second inflatable balloon portion proximal the first inflatable balloon, wherein inflation of the first and second balloon occludes a vessel between the first and second balloon;

at least one infusion opening for introducing a composition into a subject located between the first and second balloon portions;

a first electrode positioned adjacent to or integral with at least one infusion opening; and

a second electrode positioned with respect to the first electrode and the subject such that an electric field sufficient to cause electroporation of at least one cell before, during or after introduction of the composition through the at least one infusion opening.

11. (New) The catheter of claim 10, further comprising an electrical source connected to the first and second electrodes for applying a voltage between the electrodes in an amount sufficient to cause electroporation of at least one cell.

12. (New) The catheter of claim 10, wherein the vessel is a blood vessel.

13. (New) The catheter of claim 10, wherein the first electrode is formed at least in part by a biologically inert material.

14. (New) The catheter of claim 10, wherein the second electrode is a guidewire in the catheter.

15. (New) The catheter of claim 10, wherein the second electrode is a silver plate configured to be placed in contact with the subject.

16. (New) The apparatus of claim 1, wherein the at least one inflatable balloon is near the distal end of the catheter.

17. (New) An apparatus for introducing a composition into at least one cell in a vessel in a subject comprising:

a catheter having at least one inflatable balloon portion at a position other than the distal end of the catheter;

at least one infusion opening for introducing the composition into the subject;

a first electrode positioned adjacent to at least one infusion opening; and

a second electrode positioned with respect to the first electrode and the subject such that an electric field sufficient to cause electroporation of at least one cell after introduction of the composition through at least one infusion passage can be administered.

18. (New) The catheter of claim 17, further comprising an electrical source connected to the first and second electrodes for applying a voltage between the electrodes in an amount sufficient to cause electroporation of at least one cell.

19. (New) The catheter of claim 17, wherein the vessel is a blood vessel.

20. (New) The catheter of claim 17, wherein the first electrode is formed at least in part by a biologically inert material.

21. (New) The catheter of claim 17, wherein the second electrode is a guidewire in the catheter.

22. (New) The catheter of claim 17, wherein the second electrode is a silver plate configured to be placed in contact with the subject.

REMARKS

Claims 1-6 were pending before this Preliminary Amendment as filed in the Continuation Application herein. By this Preliminary Amendment, claim 1 is amended and new claims 7-22 are added as shown in Exhibit A attached hereto to define Applicants' invention with greater particularity. No new matter is added by the amendments as the new claim language is fully supported by the Specification and original claims. Applicants submit that the claim amendments do not narrow the claims in any way within the meaning of Festo Corporation v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd., a/k/a SMC Corporation and SMC Pneumatics, Inc. 234 F.3d 558, 51 U.S.P.Q. 2d 1959 (Fed. Cir. 2000). Accordingly, claims 1-22 are currently pending.

In view of the above amendments and remarks, reconsideration and favorable action on claims 1-22 are respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted,

Date: **December 14, 2001**

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EXHIBIT A

Version with Markings to Show Changes Made

In the claims

Please amend claim 1 as follows:

1. (Amended) An apparatus for introducing a composition into at least one cell in a vessel in a subject comprising:

a catheter having at least one inflatable balloon portion, wherein upon inflation, the balloon occludes the vessel;

at least one infusion [passage] opening for introducing the composition into the subject proximal to the at least one inflatable balloon portion;

a first electrode positioned adjacent to at least one infusion opening; and

a second electrode positioned with respect to the first electrode and the subject such that an electric field sufficient to cause electroporation of at least one cell [in the vessel is generated, thereby allowing the composition to enter at least one cell] after introduction of the composition through at least one infusion [passage] opening.

Please add new claims 7-22 as follows:

-- 7. (New) The apparatus of claim 1, wherein the catheter has two inflatable balloon portions.

8. (New) The apparatus of claim 7, wherein the at least one infusion opening is between the two inflatable balloon portions.

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9. (New) The apparatus of claim 1 or 8, wherein the first electrode is coincident with the at least one infusion opening.

10. (New) A catheter comprising:

a first inflatable balloon portion near the distal end of the catheter;

a second inflatable balloon portion proximal the first inflatable balloon, wherein inflation of the first and second balloon occludes a vessel between the first and second balloon;

at least one infusion opening for introducing a composition into a subject located between the first and second balloon portions;

a first electrode positioned adjacent to or integral with at least one infusion opening; and

a second electrode positioned with respect to the first electrode and the subject such that an electric field sufficient to cause electroporation of at least one cell before, during or after introduction of the composition through the at least one infusion opening.

11. (New) The catheter of claim 10, further comprising an electrical source connected to the first and second electrodes for applying a voltage between the electrodes in an amount sufficient to cause electroporation of at least one cell.

12. (New) The catheter of claim 10, wherein the vessel is a blood vessel.

13. (New) The catheter of claim 10, wherein the first electrode is formed at least in part by a biologically inert material.

14. (New) The catheter of claim 10, wherein the second electrode is a guidewire in the catheter.

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15. (New) The catheter of claim 10, wherein the second electrode is a silver plate configured to be placed in contact with the subject.

16. (New) The apparatus of claim 1, wherein the at least one inflatable balloon is near the distal end of the catheter.

17. (New) An apparatus for introducing a composition into at least one cell in a vessel in a subject comprising:

a catheter having at least one inflatable balloon portion at a position other than the distal end of the catheter;

at least one infusion opening for introducing the composition into the subject;

a first electrode positioned adjacent to at least one infusion opening; and

a second electrode positioned with respect to the first electrode and the subject such that an electric field sufficient to cause electroporation of at least one cell after introduction of the composition through at least one infusion passage can be administered.

18. (New) The catheter of claim 17, further comprising an electrical source connected to the first and second electrodes for applying a voltage between the electrodes in an amount sufficient to cause electroporation of at least one cell.

19. (New) The catheter of claim 17, wherein the vessel is a blood vessel.

20. (New) The catheter of claim 17, wherein the first electrode is formed at least in part by a biologically inert material.

21. (New) The catheter of claim 17, wherein the second electrode is a guidewire in the catheter.

22. (New) The catheter of claim 17, wherein the second electrode is a silver plate configured to be placed in contact with the subject. –